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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,290	08/30/2000	Marcin S. Filutowicz	P00154US/13238/00016	2591

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 09/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/651,290	FILUTOWICZ, MARCIN S.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 16-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-12 and 16-27* is/are rejected.

7)☒ Claim(s) *6* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 August 2000* is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is responsive to Applicant's amendment and response filed June 21, 2004. Applicant's submission of a Declaration filed under 37 C.F.R. 1.132 as well as 11 sets of data are acknowledged. Claims 1-12 and 16-27 have been amended. Claims 13-15 and 28-31 have been cancelled.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in the prior Office Action.

3. The declaration filed under 37 C.F.R. 1.132 was sufficient to overcome the rejection under 35 U.S.C. 112, first paragraph, pages 2-7, paragraph 5.

Rejections Withdrawn

4. In view of Applicant's amendment and response the following rejections are withdrawn.

a) rejection of claims 1-12 and 16-27 under 35 U.S.C. 112, first paragraph, pages 2-7, paragraph 5.

b) rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, page 7, paragraph 6.

c) rejection of claims 1, 3-5 and 7012 under 35 U.S.C. 102(b), pages 8-9, paragraph 7.

d) rejection of claims 1, 3-5 and 7-12 under 35 U.S.C. 102(b), pages 9-10, paragraph 8.

e) rejection of claims 1-12 under 35 U.S.C. 112, second paragraph, page 9, paragraph 9.

f) rejection of claims 16-27 under 35 U.S.C. 112, second paragraph, page 9, paragraph 10.

g) rejection of claims 16-27 under 35 U.S.C. 112, second paragraph, page 10, paragraph 11.

New Grounds of Rejection

Claim Objections

5. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-12 recite the: "...an origin of transfer from which conjugative transfer of the transmissible plasmid indicates from the donor bacterium to at least one recipient bacterium" (step b). It is unclear as to what the applicant is referring? Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

7. Claims 1, 3-5 and 7-12 are rejected under 35 U.S.C. 102(b) as anticipated by Mahan et al *(U.S. Patent No: 5,434, 065, published July 18, 1995).*

The claims are drawn to a recombinant donor bacterium harboring at least one transmissible plasmid comprising: an origin of replication (for synthesizing the plasmid in a bacterial cell, wherein the initiation of replication at the origin is negatively controlled by a plasmid replication repressor, wherein the absence of the plasmid replication repressor, the transmissible plasmid under goes runaway replication), an origin of transfer (from which conjugative transfer of the transmissible plasmid indicates from the donor bacterium at least one recipient bacterium) and at least one screenable marker gene.

Mahan et al teach recombinant bacteria that harbor a plasmid which is a derivative of a suicide plasmid that confers ampicillin resistance. Therefore the invention teach that the vector has a selectable marker. Mahan et al teach that the vectors of the invention also include a mob gene which contains an origin of transfer (ori T) and the origin of replication from plasmid R6K (ori R6K) (column

10). Mahan et al teach that the plasmid is supplied in trans by an *E. coli* strain (column 10). Mahan et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's recombinant bacterium with the recombinant bacterium of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant bacterium of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant bacterium). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

8. Claims 1, 3-5, 7-12 and 16-27 are rejected under 35 U.S.C. 102(e) as anticipated by Curtiss, III et al *(U.S. Patent No: 6, 780, 405 B1 published August 24, 2004).*

The claims are drawn to a recombinant donor bacterium harboring at least one transmissible plasmid comprising: an origin of replication (for synthesizing the plasmid in a bacterial cell, wherein the initiation of replication at the origin is negatively controlled by a plasmid replication repressor, wherein the absence of the plasmid replication repressor the transmissible plasmid under goes runaway replication), an origin of transfer (from which conjugative transfer of the transmissible plasmid indicates from the donor bacterium at least one recipient bacterium) and at least one screenable marker gene.

Curtiss, III et al teach recombinant bacteria that harbor a regulated antigen delivery system (RADS) which comprises a vector that includes an origin of replication repressible by a repressor (see the Abstract). Curtiss, III et al teach that the microorganisms harboring the runaway vectors (RAV) can be transferred to or expressed in another cell (column 23). Therefore the prior art meet the claim limitation (having an origin of transfer). Curtiss, III et al teach that bacteria that are used with the transfer vectors are from the genera *Shigella, Salmonella, Yersinia* or *Escherichia* (column 21). Curtiss, III et al teach that the vectors used in the invention regulate maltose and arabinose. Therefore, the vectors as taught by Curtiss, II et al teach the use of a selectable marker (column 21). Curtiss, III et al teach the use of the ColE1 gene (which is a killer gene) in the invention (column 14). The claim limitation that the killer gene is of a bacteriophage would be inherent in the teachings of the prior art. Curtiss, III et al anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's recombinant bacterium with the recombinant bacterium of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant bacterium of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant bacterium). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

9. Claims 1, 3-5 and 7-12 are rejected under 35 U.S.C. 102(e) as anticipated by Mekalanos et al *(U.S. Patent 6,254, 874, published July 3, 2001).*

The claims are drawn to a recombinant donor bacterium harboring at least one transmissible plasmid comprising: an origin of replication for synthesizing the plasmid in a bacterial cell, wherein the initiation of replication at the origin is negatively controlled by a plasmid replication repressor, wherein the absence of the plasmid replication repressor the transmissible plasmid under goes runaway replication, an origin of transfer from which conjugative transfer of the transmissible plasmid indicates from the donor bacterium at least one recipient bacterium and at least one screenable marker gene.

Mekalanos et al teach recombinant bacteria that harbor a broad range suicide vector confers ampicillin resistance. Therefore the vectors of the invention teach the use of a selectable marker. Mekalanos et al also teach that the vectors of the invention include a mob gene which contains an origin of transfer (ori T) and the origin of replication from plasmid R6K (ori R6K) (column 17). Mekalanos et al teach that the plasmid is supplied in trans by an *E. coli* strain (column 17). Mekalanos et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's recombinant bacterium with the recombinant bacterium of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant bacterium of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant bacterium).

See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

10. Claims 1-5, 7-12 and 16-27 are rejected under 35 U.S.C. 102(e) as anticipated by del Cardayre et al *(U.S. Patent No: 6, 716, 631 B1 published April 6, 2004)*.

The claims are drawn to a recombinant donor bacterium harboring at least one transmissible plasmid comprising: an origin of replication for synthesizing the plasmid in a bacterial cell, wherein the initiation of replication at the origin is negatively controlled by a plasmid replication repressor, wherein the absence of the plasmid replication repressor the transmissible plasmid under goes runaway replication, an origin of transfer from which conjugative transfer of the transmissible plasmid indicates from the donor bacterium at least one recipient bacterium and at least one screenable marker gene.

delCardayre et al teach recombinant bacteria that harboring suicide vectors that comprise an origin of replication (column 15), an origin of transfer (column 50) and a selective marker (column 15). delCardayre et al that transfer functions for mobilization from the transposon-borne oriT sites are provided by a helper vector (columns 51-52). delCardayre et al teach that bacteria used in the invention include the genera of *Bacillus, Escherichia, Streptomyces, Pseudomonas, Actinomycetes, Erwinia* and *Salmonella* (column 10). delCardayre et al teach recombinant bacteria may include a negative selective

gene (killer gene) and when the negative selective product is produced the cell is eliminated (column16). delCardayre et al, anticipate the claimed invention.

Since the Office does not have the facilities for examining and comparing applicant's recombinant bacterium with the recombinant bacterium of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the recombinant bacterium of the prior art does not possess the same material structural and functional characteristics of the claimed recombinant bacterium). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Pertinent Prior Art

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure Fujiwara et al, (U.S. Patent No. 5,399, 496) and Molin et al (European Patent Application 0109150 A2, published May 23, 1984).

Status of Claims

12. No claims allowed.

Conclusion

13. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (571) 272-0864.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
August 31, 2004

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